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**Notice of Allowability**

Application No.

08/468,145

Examiner

N. M. Minnifield

Applicant(s)

ENGEL ET AL.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 5/6/04 and 7/19/04.
2. ☒ The allowed claim(s) is/are 20-23; now renumbered 1-4 respectively.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☒ All    b) ☐ Some\*    c) ☐ None    of the:
  1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached  
1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 4/7/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date attached.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

  
N. M. Minnifield  
Primary Examiner  
Art Unit: 1645

## EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Thomas A. Cawley, 40,944 on July 19, 2004.

2. Applicants' amendment filed May 6, 2004 is acknowledged and has been entered. Claims 1-19 have been canceled. Claim 20 has been amended. Claims 20-23 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment, comments/arguments set forth in the response and the Examiner's amendment set forth below.

3. The application has been amended as follows:

1-19. (Canceled)

20. (Currently Amended) A method for the preparation of a sterile Cetrorelix lyophilizate, said method comprising the steps of

(a) dissolving Cetrorelix having the amino acid sequence of

AC-D-Nal(2)-D-pCl-Phe-D-Pal(3)-Ser-Tyr-D-Cit-Leu-Arg-Pro-D-Ala-NH<sub>2</sub>  
(SEQ ID NO: 1) in aqueous acetic acid to form a solution, [wherein the acetic acid has a pH range between 2.5-3.0,]

(b) diluting said solution with water for injection,

(c) adding bulking agent to the solution, wherein said solution has a pH range between 2.5-3.0, and

(d) sterile filtering, dispensing into injection vials and lyophilizing the solution thereby obtaining a sterile Cetorelix lyophilizate.

21. (Previously Presented) The method according to claim 20, wherein the bulking agent used is a hexitol.

22. (Previously presented) The method according to claim 21, wherein the hexitol is selected from the group consisting of mannitol, glucitol, sorbitol, D-sorbitol, dulcitol, allitol, iditol, urea or sodium chloride in an amount from 10-500 parts by weight per one part by weight Cetorelix.

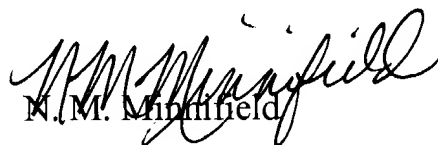
23. (Previously Presented) The method according to claim 20, wherein 1 part by weight of cetorelix acetate is dissolved in 100-10,000 parts by weight of a 30% strength (w/w) acetic acid solution and diluted with water to 3% strength aqueous acetic acid, and wherein the bulking agent is mannitol.

4. Claims 20-23 have been allowed and renumbered 1-4 respectively.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



N. M. Minnifield

Primary Examiner

Art Unit 1645

NMM

July 19, 2004